CLAIM AMENDMENTS

1. (Twice Amended) A method for detecting polymorphisms in a uridine diphosphate glucuronosyltransferase (UGT) gene promoter comprising determining the presence of either five or eight (TA) repeats in said promoter, wherein the ~~the~~ presence of five TA repeats correlates with increased expression of the gene, and the presence of eight repeats correlates with decreased expression of the gene.

9. (Twice Amended) A method for detecting polymorphisms in a uridine diphosphate glucuronosyltransferase I (UGT1A1) gene promoter comprising determining the presence of either five or eight (TA) repeats in said promoter, wherein the ~~the~~ presence of five TA repeats correlates with increased expression of the gene, and the presence of eight repeats correlates with decreased expression of the gene.

16. (Twice Amended) A method for screening individuals for variation in glucuronidation activity comprising detecting polymorphisms in a uridine diphosphate glucuronosyltransferase (UGT) gene promoter comprising determining the presence of either five or eight (TA) repeats in said promoter, wherein the ~~the~~ presence of five TA repeats correlates with increased expression of the gene, and the presence of eight repeats correlates with decreased expression of the gene.

24. (Twice Amended) A method for screening individuals for variation in glucuronidation activity comprising detecting polymorphisms in a uridine diphosphate glucuronosyltransferase I (UGT1A1) gene promoter, the method comprising determining the presence of either five or eight (TA) repeats in said promoter, wherein the ~~the~~ presence of five TA repeats correlates with increased expression of the UGT gene, and the presence of eight repeats correlates with decreased expression of the UGT gene.

75. (Once Amended) The method of claim 31 or 39~~31~~ wherein the drug is TAS-103.

PENDING CLAIMS

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1. (Twice Amended) A method for detecting polymorphisms in a uridine diphosphate glucuronosyltransferase (UGT) gene promoter comprising determining the presence of five or eight (TA) repeats in said promoter, wherein the presence of five TA repeats correlates with increased expression of the gene, and the presence of eight repeats correlates with decreased expression of the gene.

2. The method of claim 1 comprising the steps of:

(a) obtaining DNA from an individual;

(b) amplifying all or part of said UGT1A1 gene promoter contained in said DNA; and

(c) determining the number of TA repeats in said promoter.

3. The method of claim 1 or 2 wherein said promoter is the UGT1A1 promoter.

4. The method of claim 3 wherein said DNA being amplified comprises all or part of a UGT1A1 promoter.

5. The method of claim 1 wherein said DNA is amplified by the polymerase chain reaction (PCR) and said number of TA repeats is determined by gel electrophoresis.

6. The method of claim 1 wherein said DNA is amplified by PCR and said number of TA repeats is determined by sequencing said amplified DNA.

8. The method of claim 1 wherein said promoter has a genotype selected from the group consisting of $[TA]_5$ / $[TA]_5$, $[TA]_5$ / $[TA]_6$, $[TA]_5$ / $[TA]_7$, $[TA]_5$ / $[TA]_8$, $[TA]_6$ / $[TA]_8$, $[TA]_7$ / $[TA]_8$, and $[TA]_8$, / $[TA]_8$.

9. (Twice Amended) A method for detecting polymorphisms in a uridine diphosphate glucuronosyltransferase I (UGT1A1) gene promoter comprising determining the presence of five or eight (TA) repeats in said promoter, wherein the presence of five TA repeats correlates with

increased expression of the gene, and the presence of eight repeats correlates with decreased expression of the gene.

10. The method of claim 9 comprising the steps of:

(a) obtaining DNA from an individual;

(b) amplifying all or part of said UGT gene promoter contained in said DNA; and

(c) determining the number of TA repeats in said promoter.

11. The method of claim 9 wherein said DNA being amplified comprises all or part of a UGT1A1 promoter.

12. The method of claim 9 wherein said DNA is amplified by polymerase chain reaction (PCR) and said number of TA repeats is determined by gel electrophoresis.

13. The method of claim 9 wherein said DNA is amplified by PCR and said number of TA repeats is determined by sequencing said amplified DNA.

15. The method of claim 9 wherein said promoter has a genotype selected from the group consisting of $[TA]_5$ / $[TA]_5$, $[TA]_5$ / $[TA]_6$, $[TA]_5$ / $[TA]_7$, $[TA]_5$ / $[TA]_8$, $[TA]_6$ / $[TA]_8$, $[TA]_7$ / $[TA]_8$, and $[TA]_8$, / $[TA]_8$.

16. (Twice Amended) A method for screening individuals for variation in glucuronidation activity comprising detecting polymorphisms in a uridine diphosphate glucuronosyltransferase (UGT) gene promoter comprising determining the presence of five or eight (TA) repeats in said promoter, wherein the presence of five TA repeats correlates with increased expression of the gene, and the presence of eight repeats correlates with decreased expression of the gene.

17. The method of claim 16 comprising the steps of:

(a) obtaining DNA from an individual;

(b) amplifying all or part of said UGT gene promoter contained in said DNA; and

(c) determining the number of TA repeats in said promoter.

18. The method of claim 16 or 17 wherein said promoter is the UGT1A1 promoter.

19. The method of claim 18 wherein said DNA being amplified comprises all or part of a UGT1Al promoter.

20. The method of claim 16 wherein said DNA is amplified by the polymerase chain reaction (PCR) and said number of TA repeats is determined by gel electrophoresis.

21. The method of claim 16 wherein said DNA is amplified by PCR and said number of TA repeats is determined by sequencing said amplified DNA.

23. The method of claim 16 wherein said promoter has a genotype selected from the group consisting of $[TA]_5$ / $[TA]_5$, $[TA]_5$ / $[TA]_6$, $[TA]_5$ / $[TA]_7$, $[TA]_5$ / $[TA]_8$, $[TA]_6$ / $[TA]_8$, $[TA]_7$ / $[TA]_8$, and $[TA]_8$, / $[TA]_8$.

24. (Twice Amended) A method for screening individuals for variation in glucuronidation activity comprising detecting polymorphisms in a uridine diphosphate glucuronosyltransferase I (UGT1A1) gene promoter, the method comprising determining the presence of five or eight (TA) repeats in said promoter, wherein the presence of five TA repeats correlates with increased expression of the UGT gene, and the presence of eight repeats correlates with decreased expression of the UGT gene.

25. The method of claim 24 comprising the steps of

(a) obtaining DNA from an individual;

(b) amplifying all or part of said UGT gene promoter contained in said DNA; and

(c) determining the number of TA repeats in said promoter.

26. The method of claim 24 wherein said DNA being amplified comprises all or part of a UGT1A1 promoter.

27. The method of claim 24 wherein said DNA is amplified by polymerase chain reaction (PCR) and said number of TA repeats is determined by gel electrophoresis.

28. The method of claim 24 wherein said DNA is amplified by PCR and said number of TA repeats is determined by sequencing said amplified DNA.

30. The method of claim 24 wherein said promoter has a genotype selected from the group consisting of $[[TA]_5 / [TA]_5$, $[TA]_5 / [TA]_6$, $[TA]_5 / [TA]_7$, $[TA]_5 / [TA]_8$, $[TA]_6 / [TA]_8$, $[TA]_7 / [TA]_8$, and $[TA]_8, / [TA]_8$.

31. A method for optimizing drug dosages for a patient wherein said drugs are glucuronidated by a uridine diphosphate glucuronosyltransferase (UGT), said method comprising determining the number of thymidine-adenine (TA) repeats in a promoter of the UGT gene wherein the number of TA repeats correlates with expression of said UGT gene, and wherein the, activity of said drug is effected by its level of glucuronidation.

32. The method of claim 31 comprising the steps of:

(a) obtaining DNA from an individual;

(b) amplifying all or part of said UGT gene promoter contained in said DNA; and

(c) determining the number of TA repeats in said promoter.

33. The method of claim 31 or 32 wherein said promoter is the UGT1A1 promoter.

34. The method of claim 32 wherein said DNA being amplified comprises 0 or part of a UGT1Al promoter.

35. The method of claim 31 wherein said DNA is amplified by the polymerase chain reaction (PCR) and said number of TA repeats is determined by gel electrophoresis.

36. The method of claim 31 wherein said DNA is amplified by PCR and said number of TA repeats is determined and sequencing said amplified DNA.

37. The method of claim 31 wherein said polymorphism comprises an allele, said allele selected from the group consisting of five TA repeats, $[TA]_5$, six TA repeats, $[TA]_6$, seven TA repeats, $[TA]_7$ and eight TA repeats, $[TA]_8$.

38. The method of claim 31 wherein said promoter has a genotype selected from the group consisting of $[TA]_5$ / $[TA]_5$, $[TA]_5$ / $[TA]_6$, $[TA]_5$ / $[TA]_7$, $[TA]_5$ / $[TA]_8$, $[TA]_6$ / $[TA]_8$, $[TA]_7$ / $[TA]_8$, and $[TA]_8$, / $[TA]_8$.

39. A method for optimizing drug dosages wherein said drugs are glucuronidated by uridine diphosphate glucuronosyltransferase I, said method comprising determining the number of thymidine-adenine (TA) repeats in a promoter of the UGT1 gene wherein the number of TA repeats correlates with expression of said UGT gene, and wherein the activity of said drug is effected by its level of glucuronidation.

40. The method of claim 39 comprising the steps of:

(a) obtaining DNA from an individual;

(b) amplifying all or part of said UGT gene promoter contained in said DNA; and

(c) determining the number of TA repeats in said promoter.

41. The method of claim 39 or 40 wherein said promoter is the UGT1A1 promoter.

42. The method of claim 39 wherein said DNA being amplified comprises all or part of a UGT1A1 promoter.

43. The method of claim 39 wherein said DNA is amplified by the polymerase chain reaction (PCR) and said number of TA repeats is determined by gel electrophoresis.

44. The method of claim 39 wherein said DNA is amplified by PCR and said number of TA repeats is determined by sequencing said amplified DNA.

45. The method of claim 39 wherein said polymorphism comprises an allele, said allele selected from the group consisting of five TA repeats, $[TA]_5$, six TA repeats, $[TA]_6$, seven TA repeats, $[TA]_7$ and eight TA repeats, $[TA]_8$.

46. The method of claim 39 wherein said promoter has a genotype selected from the group consisting of $[TA]_5$ / $[TA]_5$, $[TA]_5$ / $[TA]_6$, $[TA]_5$ / $[TA]_7$, $[TA]_5$ / $[TA]_8$, $[TA]_6$ / $[TA]_8$, $[TA]_7$ / $[TA]_8$, and $[TA]_8$, / $[TA]_8$.

47. A method for predicting an individual's sensitivity to xenobiotics wherein said xenobiotics are glucuronidated by a uridine diphosphate glucuronosyltransferase gene product, said method comprising determining the number of thymidine-adenine (TA) repeats in a UGT gene promoter, wherein the number of TA repeats correlates with expression of said UGT gene and wherein the individual's sensitivity to said xenobiotics is effected by glucuronidation activity.

48. The method of claim 47 comprising the steps of:

(a) obtaining DNA from an individual;

(b) amplifying all or part of said UGT gene promoter contained in said DNA; and

(c) determining the number of TA repeats in said promoter.

49. The method of claim 47 or 48 wherein said promoter is the UGT1A1 promoter.

50. The method of claim 47 wherein said DNA being amplified comprises all or part of a UGT1Al promoter.

51. The method of claim 47 wherein said DNA is amplified by the polymerase chain reaction (PCR) and said number of TA repeats is determined by gel electrophoresis.

52. The method of claim 47 wherein said DNA is amplified by PCR and said number of TA repeats is determined by sequencing said amplified DNA.

53. The method of claim 47 wherein said polymorphism comprises an allele, said allele selected from the group consisting of five TA repeats, $[TA]_5$, six TA repeats, $[TA]_6$, seven TA repeats, $[TA]_7$ and eight TA repeats, $[TA]_8$.

54. The method of claim 47 wherein said promoter has a genotype selected from the group consisting of $[TA]_5$ / $[TA]_5$, $[TA]_5$ / $[TA]_6$, $[TA]_5$/$[TA]_7$, $[TA]_5$ / $[TA]_8$, $[TA]_6$ / $[TA]_8$, $[TA]_7$ / $[TA]_8$ and $[TA]_8$ / $[TA]_8$.

55. A method for predicting an individual's sensitivity to xenobiotics wherein said xenobiotics are glucuronidated by a uridine diphosphate glucuronosyltransferase I gene product, said method comprising determining the number of thymidine-adenine (TA) repeats in a UGT1

gene promoter, wherein the number of TA repeats correlates with expression of said UGT1 gene and wherein the individual's sensitivity to said xenobiotics is effected by glucuronidation activity.

56. The method of claim 55 comprising the steps of:

(a) obtaining DNA from an individual;

(b) amplifying all or part of said UGT1 gene promoter contained in said DNA; and

(c) determining the number of TA repeats in said promoter.

57. The method of claim 55 or 56 wherein said promoter is the UGT1A1 promoter.

58. The method of claim 55 wherein said DNA being amplified comprises all or part of a UGT1A1 promoter.

59. The method of claim 55 wherein said DNA is amplified by the polymerase chain reaction (PCR) and said number of TA repeats is determined by gel electrophoresis.

60. The method of claim 55 wherein said DNA is amplified by PCR and said number of TA repeats is determined by sequencing said amplified DNA.

61. The method of claim 55 wherein said polymorphism comprises an allele, said allele selected from the group consisting of five TA repeats, $[TA]_5$, six TA repeats, $[TA]_6$, seven TA repeats, $[TA]_7$ and eight TA repeats, $[TA]_8$.

62. The method of claim 55 wherein said promoter has a genotype selected from the group consisting of $[TA]_5$ / $[TA]_5$, $[TA]_5$ / $[TA]_6$, $[TA]_5$ / $[TA]_7$, $[TA]_5$ / $[TA]_8$, $[TA]_6$ / $[TA]_8$, $[TA]_7$ / $[TA]_8$, and $[TA]_8$, / $[TA]_8$.

70. The method of claim 1, 9, 16, 24, 31, 39, 47 or 55, wherein the method comprises determining the presence of five TA repeats in said promoter.

71. The method of claim 1, 9, 16, 24, 31, 39, 47 or 55, wherein the method comprises determining the presence of eight TA repeats in said promoter.

72. The method of claim 1, 9, 16, 24, 31, 39, 47 or 55, further comprising determining the presence of six TA repeats, $[TA]_6$, in said promoter.

73. The method of claim 1, 9, 16, 24, 31, 39, 47 or 55, further comprising determining the presence of seven TA repeats, $[TA]_7$, in said promoter.

74. The method of claim 31 or 39, wherein the drug is Irinotecan.

75. The method of claim 31 or 31 wherein the drug is TAS-103.